

REMARKS

Claims 20, 22-31 and 29-31 are pending in the present application, with claims 23-28 being withdrawn. Claims 20 and 22 have been amended herein.

Rejections under 35 U.S.C. §112, 2nd paragraph

Claims 20, 22 and 29-31 have been rejected under 35 U.S.C. §112, 2nd paragraph as being unclear. More specifically, the Examiner raises the following issues regarding the claims.

a) The Examiner asserts that claim 20 is missing an essential step to the invention. The Examiner is of the position that there should be an additional step between steps (ii) and (iii), which defines how the transformed host cells are selected. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

The invention of amended claim 20 is drawn to a method for isolating a desired gene, which comprises

(i) inserting DNA fragments obtained from DNA containing the desired gene into a plasmid vector(s) comprising a promoter sequence to control an expression of a desired gene, said promoter sequence being recognized by an RNA polymerase derived from SP6 phage, and a replication origin for increasing a copy number by

induction with an exogenous factor, said replication origin comprising lac promoter and RNAII region, wherein said desired gene encodes a protein lethal or harmful to the host;

(ii) transforming host cells with the resulting vector(s) of step (i) ; and

(iii) selecting the transformed host cells containing said desired gene.

The invention, as recited in claim 20, requires that the desired gene encoding a protein lethal or harmful to the host can be maintained in the host cell until the desired timing of protein expression. As such, one skilled in the art can readily confirm which cells are transformed with the gene by detecting the presence of the gene in the host cell. The specific method by which the transformed host cell is selected is not an essential feature of the invention and therefore does not need to be recited in claim 20. Withdrawal of the rejection is respectfully requested.

b) The Examiner further asserts that claim 20 needs to recite a step of selecting DNA fragments containing the entire desired gene, such that fragments containing the entire gene are differentiated from DNA fragments containing none of or less than

the entire gene. Applicants traverse this rejection and withdrawal thereof is respectfully requested.

M.P.E.P. §2172.01 states that "a claim which fails to interrelate essential elements of the invention as defined by applicant(s) in the specification may be rejected under 35 U.S.C. 112, second paragraph, for failure to point out and distinctly claim the invention. See *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968)." However, nowhere in the specification do Applicants teach or suggest that the method by which the inserted DNA fragment is selected from DNA containing the gene is an essential element of the invention.

Claim 20 recites "inserting DNA fragments obtained from DNA containing the desired gene into a plasmid vector(s)." The Examiner is directed to the discussion of "essential steps" offered by the Board of Patent Appeals & Interferences in Ex parte Quattlebaum 84 USPQ 377 (Bd. Pat. App. & Int. 1948). The Board of Appeals note in Quattlebaum that a step is only essential if it is "essential to assure even a small degree of operativeness." Even without a step of selecting for fragments containing the entire gene rather than a gene fragment, the invention would be operative, even if not as efficiently. However, claims are not required to be written for optimal efficiency of practice, but simply to be clear and operative. Claim 20 is both clearly defined and operative. As

such, the requirements for 35 U.S.C. §112 are met and withdrawal of the rejection is respectfully requested.

c) Claim 20 has been rejected for containing a typographical error in the recitation of "of". Claim 20 has been amended to correct this error. Withdrawal of the rejection is respectfully requested.

d) Claim 22 has been rejected for depending from cancelled claim 21. Claim 22 has been amended to depend from claim 20. Withdrawal of the rejection is respectfully requested.

e) Claim 30 has been rejected as being vague in the recitation of "obtaining a DNA fragment containing by PCR-based amplification...." The Examiner asserts that it is unclear what is encompassed by the PCR protocol. The Examiner specifically notes that it is unclear whether the DNA containing the desired gene is used as a primer. Applicants traverse this rejection and withdrawal thereof is respectfully requested. Claim 30 has been amended for clarity to recite "PCR."

PCR is well-known technique, such that the meaning of the term "PCR" would be readily evident to one skilled in the art and

specific PCR steps do not need to be recited in the claim. Withdrawal of the rejection is respectfully requested.

f) Claim 31 has been rejected as lacking antecedent basis in 22 for the term "said plasmid vector." Antecedent basis for "said plasmid vector" is found in claim 20, from which claim 22 now depends. Withdrawal of the rejection is respectfully requested.

As the rejections have been fully addressed and overcome, withdrawal thereof and allowance of the claims is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact MaryAnne Armstrong, PhD (Reg. No. 40,069) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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